Proposed Decision Memo for Cardiac Catheterization Performed In Other Than A Hospital Setting (CAG-00166N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes to repeal the National Coverage Determination (NCD) Manual §20.25.

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Proposed Decision Memo

TO: Administrative File CAG: # 00166N Cardiac Catheterization Performed In Other Than A Hospital Setting

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SUBJECT: Coverage Decision Memorandum for Cardiac Catheterization Performed In Other Than a Hospital Setting

DATE: October 21, 2005

I. Decision

The Centers for Medicare and Medicaid Services (CMS) proposes to repeal the National Coverage Determination (NCD) Manual §20.25.

II. Background and History of Medicare Coverage

The Medicare National Coverage Policy for Cardiac Catheterization Performed In Other

Than A Hospital Setting was implemented August 1, 1979 in the NCD Manual §20.25:

Cardiac catheterization performed in a hospital setting for either inpatients or outpatients is a covered service. The procedure may also be covered when performed in a freestanding clinic when the carrier, in consultation with the appropriate Peer Review Organization (PRO), determines that the procedure can be performed safely in all respects in the particular facility. Prior to approving Medicare payment for cardiac catheterizations performed in freestanding clinics, carriers must request PRO review of the clinic.[1]

At that time, the carriers (Medicare Part B contractors) were responsible for consulting with the PROs (subsequently renamed Quality Improvement Organizations [QIOs]) prior to approving Medicare payment. In 1979, the PROs were conducting reviews as part of their scope of work. In the early 1990's, the approach and functions of the PROs changed from case reviews to quality improvement. The PROs stopped their review of freestanding cardiac catheterization facilities when it was no longer included in the PRO scope of work in 1995. The language in the NCD Manual was never revised to reflect the change in QIO functions. Therefore, the policy that remains in the NCD Manual contains outdated language that implies QIO activity outside their scope of work.

III. Timeline

8/1/79	CMS implemented the national policy for cardiac catheterization in other than a hospital setting requiring PRO involvement.

1995	Review of cardiac catheterization facilities was no longer included in the PRO scope of work.
10/8/02	CMS opened the NCD and requested public comment.
1/16/03	CMS extended the due date of the NCD.
2/10/03	CMS extended the due date of the NCD.

IV. Evidence

PubMed was searched from 1999 using the term "cardiac catheterization laboratory". Within this time period, no controlled trials were identified comparing patient outcomes and safety of cardiac catheterizations performed in freestanding facilities with hospital-based procedures. The search did identify, however, a consensus document from the American College of Cardiology (ACC) and The Society for Cardiac Angiography and Interventions (SCA&I) and an article discussing trends in the growing number of freestanding facilities in the United States[2].

Guidelines, consensus panels and expert opinion

The ACC/SCA&I Clinical Expert Consensus Document: Cardiac Catheterization Laboratory Standards discusses recommended requirements for performing cardiac catheterizations in freestanding facilities. The freestanding facility should have a formal relationship with a tertiary hospital for the emergency transfer of patients, have equipment for intubation and ventilatory support, and have quality assurance and quality improvement programs in place. In addition, the physicians must be able to perform endotracheal intubations and insert an intra-aortic balloon pump. Patient selection is critically important in freestanding facilities without surgical backup, and is specifically addressed in the document. The consensus document recommends that only diagnostic cardiac catheterizations be performed in freestanding facilities and lists patient inclusion and exclusion criteria; no therapeutic procedures are recommended.

The ACC and SCA&I document stresses the importance of quality assurance outlining clinical proficiency, complication rate, diagnostic accuracy and patient outcomes as critical aspects of a cardiac catheterization lab. The document reports that the major complication rate for diagnostic cardiac catheterizations is estimated between 1% and 2%, which the experts feel is acceptably low[3].

External Technology Assessment

In 2005, the Agency for Healthcare Research and Quality commissioned a technology assessment on cardiac catheterization in freestanding clinics to answer 5 key questions:

1. Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for diagnostic catheterization procedures?
2. Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for interventional catheterization procedures?
3. Do hospitals without cardiac surgical support and hospitals with cardiac surgical support have comparable complication rates for diagnostic and interventional catheterization procedures?
4. What are the characteristics of patients who have had catheterization procedures in freestanding cardiac catheterization clinics vs. hospitals?
5. What are the current state regulations, Certificate of Need (CON) requirements, and oversight procedures for freestanding cardiac catheterization clinics?

The assessment was performed by ECRI and stated (reproduced exactly from the report[4]):

"Key Question 1: Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for diagnostic catheterization procedures?

After searching the literature, retrieving articles, and applying the inclusion/exclusion criteria, we identified 23 publications that reported complication rates of diagnostic catheterization procedures in a freestanding or hospital outpatient setting. None of these studies directly compared complication rates in freestanding and hospital settings. Thus, the quality of the evidence is low. The studies' generalizability to the Medicare population was fair.

Five separate studies reported complications in a freestanding laboratory (two of these studies were reported only in a systematic review but have not been otherwise published). The mortality rates ranged from 0 to 0.16%, as did the rate of MI, while the rate of stroke/transient ischemic attack (TIA) ranged from 0 to 0.03%. Vascular complications ranged from 0 to 2.0%.

Nineteen studies reported complication rates in a mobile or fixed hospital outpatient setting. No deaths occurred in any of the three mobile laboratory studies, while the mortality rate ranged from 0 to 0.3% among the 16 fixed hospital outpatient studies. Rates of MI ranged from 0 to 0.1% in mobile labs and 0 to 0.7% in fixed outpatient settings, while rates of stroke/transient ischemic attack (TIA) ranged from 0 to 0.3% in mobile labs and 0 to 0.4% in fixed outpatient clinics. Rates of vascular complications ranged from 0 to 0.1% in mobile labs and 0 to 2.0% in fixed outpatient settings.

The available evidence did not reveal substantial differences in complication rates of diagnostic catheterization procedures among freestanding clinics and hospital outpatient settings. However, this indirect and informal comparison of low quality studies could not be risk-adjusted to compensate for differences in patient characteristics among the studies. Also, none of the freestanding clinic studies reported the length of followup; if it was shorter than the average followup in the hospital outpatient studies, this would create bias in the comparison. Furthermore, we cannot determine whether the relatively low complication rates reported in freestanding studies are generalizable to all freestanding centers, as this evidence base was susceptible to potential publication bias. Since all freestanding clinic studies and most hospital outpatient studies were published in the 1980s, the degree of relevance of the findings to current clinical practice is also unknown. These weaknesses in the evidence base mean that we cannot completely rule out the possibility of differences in complication rates between these settings.

Key Question 2: Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for interventional catheterization procedures?

Our literature searches identified no studies that addressed this question. No evidence- based conclusion was possible regarding interventional catheterization procedures in freestanding centers. An American College of Cardiology (ACC)/Society for Cardiac Angiography and Interventions (SCAI) consensus document recommended that such procedures not be performed in freestanding settings, and we found no information to suggest that percutaneous coronary intervention (PCI) procedures are currently being performed in this setting.

Key Question 3: Do hospitals without cardiac surgical support and hospitals with cardiac surgical support have comparable complication rates for diagnostic and interventional catheterization procedures? This question will only be addressed if the literature is insufficient for questions 1 and/or 2 for freestanding clinics.

Because no evidence was available to address Key Question 2, we evaluated outcomes of PCI procedures at hospitals with and without surgical support. However, hospitals without cardiac surgical support are an imperfect surrogate for freestanding clinics, because even hospitals without cardiac surgical support have support services and resources beyond what is typically found in freestanding settings. Thus, one cannot be certain to what extent, if any, the findings for interventional procedures in a hospital setting can be extrapolated to a freestanding setting.

We identified seven retrospective controlled studies (five articles and two meeting abstracts) that compared complication rates of non-primary or primary PCI in hospitals with or without cardiac surgical support. These studies ranged from low to fair in quality based on U.S. Preventive Services Task Force (USPSTF) ratings. All were vulnerable to potential selection bias from lack of randomization and lack of followup of patients transferred to other hospitals. Generalizability to the Medicare population was fair except for one study where it was high.

Three studies of non-primary PCI (PCI for reasons other than emergent acute MI) reported conflicting results. One of these studies exclusively evaluated elective PCI procedures and found no statistically significant differences in complication rates between care settings. The remaining two studies evaluated all non-primary PCI procedures (including some emergent procedures). The only study that exclusively evaluated Medicare patients showed a significantly higher mortality rate in hospitals without cardiac surgical support, while the remaining study showed no significant difference between care settings. However, the latter study was low quality because no adjustments were made to account for baseline differences in the characteristics of patients who were seen at the differing hospital settings. Because these studies were vulnerable to selection bias and differed from each other in several characteristics, the conflicting results cannot be explained with certainty.

Six studies of primary PCI showed consistent findings of no statistically significant difference in rates of mortality or serious morbidity between hospitals with and without cardiac surgical backup. Three of the studies adjusted for differences in patient risk. However, all of these studies were vulnerable to selection bias to a greater or lesser degree, and some may have lacked adequate statistical power to detect a meaningful difference in rates. These flaws in the evidence base mean that failure to demonstrate a difference does not eliminate the possibility that a difference may exist.

Key Question 4: What are the characteristics of patients who have had catheterization procedures in freestanding cardiac catheterization clinics vs. hospitals?

We found no studies that directly addressed this question, but 17 of 23 studies from Key Question 1 indirectly addressed the question through their patient inclusion/exclusion criteria. The quality of these studies was low, and their generalizability to the Medicare population was fair.

Two studies of freestanding facilities reported detailed inclusion/exclusion criteria,and these criteria were very similar to those reported in hospital outpatient studies. Both freestanding and hospital outpatient studies included clinically stable patients and excluded one or more subgroups of higher risk patients (with recent MI, Class IV cardiac disease, refractory unstable angina, and severe congestive heart failure, among others). Minor variability appeared in the specific subgroups of patients excluded among the different studies.

An ACC/SCAI expert consensus document recommended similar but slightly more stringent exclusion criteria for freestanding settings than for hospitals without cardiac surgical support. A published multivariable model for predicting complication risks during cardiac catheterization procedures is consistent with some of these recommendations.

Key Question 5: What are the current state regulations, Certificate of Need (CON) requirements, and oversight procedures for freestanding cardiac catheterization clinics? Include a table summarizing regulations from all 50 states. Include also a review of international regulations and guidelines; at a minimum include information from the U.K. and Canada.

Currently, 37 states (plus Washington, D.C.) do not prohibit diagnostic cardiac catheterization procedures in a freestanding setting. In these states, regulation usually occurs through certificate of need (CON) programs (16 states plus D.C.). Sixteen states without CON programs have no regulations or licensure requirements for such clinics. Sources in 13 states (plus D.C.) that do not prohibit freestanding catheterization services reported that there were no such facilities (or at least they were not aware of any) currently operating in these states.

Thirteen states have regulations prohibiting cardiac catheterization in freestanding clinics. In three of these states, pilot programs or regulatory loopholes have allowed at least one freestanding facility to perform cardiac catheterization procedures. Any facility performing cardiac catheterization procedures can voluntarily seek Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation. The facility must meet several functional standards to gain accreditation.

Our survey of two other countries revealed that the United Kingdom does not allow any cardiac catheterization procedures to be performed outside of a hospital setting. Canada has no specific regulatory prohibitions on the national level, and four provinces did not report specific prohibitions, but all four provinces reported that no freestanding facilities were performing cardiac catheterization procedures. We cannot confirm whether any freestanding facilities perform these procedures in the remaining nine Canadian provinces and territories.”

Public Comments

CMS received comments in support of this change jointly from the ACC and SCA&I. The ACC and SCA&I acknowledge that due to changes in their scope of work, PROs have not provided oversight of freestanding facilities and that procedures have continued to be performed safely. They included in the comments a copy of the ACC/SCA&I Clinical Expert Consensus Document: Cardiac Catheterization Laboratory Standards.[5]

The American Hospital Association (AHA) submitted comments expressing concern over the lack of quality controls in outpatient facilities and suggesting that freestanding cardiac catheterization facilities be subject to quality standards and monitoring/enforcement requirements that are comparable to those applied to hospital outpatient departments for similar procedures. AHA also states that there is an inherently greater risk in performing the procedure in an outpatient setting where there are no emergency or cardiac surgery services on site.

V. CMS Analysis

National coverage determinations (NCDs) are determinations made by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1862(l)(6)(A). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

The original coverage policy for cardiac catheterization performed in freestanding centers in 1979 was developed at a time when the PROs (now known as QIOs) were conducting facility reviews as part of their scope of work. In the early 1990's, the approach and functions of the PROs changed from case reviews to quality improvement. In 1995, the review of freestanding cardiac catheterization was removed from the PRO scope of work, effectively ending PRO review of these clinics. The language in the NCD Manual was not yet revised to reflect the change in current QIO functions. Thus CMS initiated this decision to update the NCD Manual based on current evidence and practice.

When considering the evidence, specifically the AHRQ technology assessment, nearly half of the states either prohibit diagnostic cardiac catheterization in freestanding settings or have regulations or licensing programs that have prevented programs from being established. The technology assessment found that 13 states have regulations specifically prohibiting cardiac catheterization in freestanding clinics, although three of these states do have such facilities. Further, it appears that ongoing review and monitoring of cardiac catheterizations performed in freestanding clinics continues in many states. The regulation and review of the freestanding clinics that do these procedures has correctly resided with the states. If a need arises for review, QIOs can still assist with this activity as part of their discretionary local functions. CMS concludes that the NCD Manual should not reflect inaccurate QIO functions.

As noted in the technology assessment, there is suggestive but insufficient evidence to determine if net health outcomes of cardiac catheterizations performed in freestanding clinics is comparable to for cardiac catheterizations performed in the hospital setting. Comparative evidence on coronary catheter-based interventions was insufficient as well. Until a more complete evaluation of the safety and effectiveness of cardiac catheterizations performed in freestanding clinics is conducted, it appears prudent to consider the risks and benefits on a state by state basis. Therefore, we conclude that cardiac catheterization may be covered when performed in a freestanding clinic at carrier discretion. Local carrier discretion prevails in the event CMS does not have national policy on a particular service. Therefore, rather than propose national policy that explicitly states contractor discretion regarding coverage this service, CMS proposes that the existing national policy on cardiac catheterization in freestanding clinics be repealed.

VI. Conclusion

The Centers for Medicare and Medicaid Services (CMS) proposes to repeal the National Coverage Determination (NCD) Manual §20.25.

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[1] NCD Manual §20.25

[2] Sheldon, WC et al. 2001

[3] Bashore, TM et al. 2001

[4] AHRQ, 2005. Cardiac Catheterization in Freestanding Clinics, pages 1-6.

[5] Bashore, TM et al. 2001

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